

USSN 10/522,215  
Attorney Docket No. 65321(54558)

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**REMARKS**

Claims 19-21 and 28-47 are pending in the application, with claims 19-27, 38-40 and 42 withdrawn from consideration. Claims 19-21 have been cancelled without prejudice or claims, claims 28 and 44 have been amended and claims 48-59 have been added. Accordingly, claims 28-59 will be pending in the application upon entry of the amendments and presented herein.

Claims 28, 29 and 44 have been amended and claims 48-59 have been added to claim more fully and clearly the instant invention and/or to correct typographical errors. Support for the claim amendments and additions can be found throughout the specification, claims and drawings as originally filed. Unless otherwise specified, reference herein to a specification page number refers to the specification published as WO 2004/006966 (PCT/IB2003/002785).

In particular, support for the amendment of claim 28 can be found at least, for example, in the specification at pages 6-7, bridging paragraph, and at page 5, line 18. In addition, support for claims 48-59 can be found at least, for example, in the specification at page 5, lines 16-19 and in pending claims 28-37, and 43. No new matter has been added.

Amendment and cancellation of the claims should in no way be construed as an acquiescence to any of the rejections set forth in the instant Office Action, and were done solely to expedite prosecution. Applicant reserves the right to pursue the claims as originally filed in this or one or more separate applications.

***Priority Claim Under 35 USC § 119 (a)-(d) or (f)***

Applicant respectfully requests that the Office acknowledge priority to Greek Patent Application No. 20020100335 (as filed on July 16, 2002) on the record. Applicant believes the Office has received the requisite priority document(s). If however further evidence of the priority filing is needed, Applicant requests notification of same so that appropriate documentation can be obtained and sent to the Office.

***Claim Rejections - 35 USC § 112***

Claims 28-37, 40, 41 and 43-47 are rejected under 35 USC § 112, second paragraph, as allegedly being indefinite for failing to point out particularly and claim distinctly the subject matter which Applicant regards as the invention. In particular, the Examiner alleges

USSN 10/522,215  
Attorney Docket No. 65321(54558)

that claim 28 is indefinite because of the recitation "composition is conjugated" and claim 44 is indefinite because the claim, as written, could be interpreted to mean that the composition is not actually administered to the patient. Applicant respectfully disagrees.

However, without acquiescing to the rejection and in order to expedite prosecution, claim 28 has been amended, in view of the Examiner's concerns, *i.e.*, the claim now features a steroid covalently attached (bonded) to a protein. Support for the amendment can be found in the specification at least, for example, at pages 6-7, bridging paragraph. Likewise, claim 44 has been amended, in accordance with the Examiner's helpful suggestion, to recite "A method for treating prostate cancer comprising administering to a patient in need thereof a composition comprising..." Claim 28 has been similarly amended.

Applicant submits that amended claims 28 and 44, and the claims dependent thereon, meet the requirements of 35 USC § 112, second paragraph. Applicant, therefore, respectfully requests reconsideration and withdrawal of the rejection.

#### ***Claim Rejections - 35 USC § 103***

Claims 28-32, 34, 40, 41, and 43 are rejected under 35 USC § 103 as obvious over U.S. Patent 6,740,304 to Larsen ("Larsen") in view of U.S. Patent 5,157,049 to Haugwitz ("Haugwitz"), U.S. Patent 5,248,796 to Chen ("Chen") or U.S. Patent 4,960,790 to Stella ("Stella"). Applicant notes that the pending claims 33, 35, 36 and 44-47 are not subject to the rejection.

As cited, Larson discloses receptor-binding conjugates consisting of an antibody, a radionuclide and folate or a folate derivative, and the use of such conjugates to deliver therapeutic radiation to a malignant cell. The Examiner indicates that Larson discloses an immunoconjugate that can contain a steroid such as estrogen or testosterone instead of folate or a folate derivative, although the Examiner admits that Larson does not teach or suggest combining the conjugates with taxol. However, the Examiner cites the secondary references that disclose that taxol can be used to treat cancer and concludes that it would have been obvious to one of ordinary skill to combine the two agents for additive effects. Applicant respectfully disagrees.

However, without acquiescing to the rejection and in order to expedite prosecution of the instant application, claim 28 has been amended to exclude antibody proteins. Support for the amendment to claim 28 can be found in the specification at least, for example, on page 5, line 18 (disclosing an antibody as one of a number of suitable mammalian proteins). *See also*

USSN 10/522,215  
Attorney Docket No. 65321(54558)

MPEP 2173.05(i) (providing for exclusion of an element recited in a claim where Applicant has positively recited that element as one of a number of alternative elements in the specification).

Accordingly, claim 28, as amended herein, and claims 29-32, 34, 40, 41, and 43 dependent thereon, do not encompass an antibody. Applicants submit that these claims are not obvious in view of Larson, taken alone or in combination with the secondary references.

In order to establish a *prima facie* showing of obviousness, the Examiner must show that there is some motivation, provided by the cited references or by the state of the art at the time the instant application was filed, that would cause one of ordinary skill in the art to combine and/or modify the teachings of the references to arrive at the claimed invention. It is not sufficient that one of ordinary skill in the art *could* combine or modify the teachings of the references. The motivation must be such that one of ordinary skill in the art should combine or modify the teachings of the references. Moreover, the combination of references must provide each and every element of the claimed invention as well as provide one of ordinary skill in the art with a reasonable expectation of success in practicing the invention as claimed.

There is nothing in either Larson or the secondary references to suggest that one of ordinary skill in the art *should* substitute the antibody of Larson with a mammalian protein other than an antibody of the instant invention. A combination of Larson with any of the secondary references would not provide each and every element of the claims at issue because none of the references teaches or suggests the use of a mammalian protein other than an antibody. Moreover, the combination of references would not provide one of ordinary skill in the art with a reasonable expectation of success in practicing the claimed invention because none of the cited references enables the use of a mammalian protein other than an antibody.

Applicant respectfully submits that the Examiner has failed to establish a *prima facie* showing of obviousness. Applicant further submits that the rejection is moot as to claim 28, as amended herein, and claims 29-32, 34, 40, 41, and 43 dependent thereon, and, therefore, respectfully requests reconsideration and withdrawal of the rejection.

USSN 10/522,215  
Attorney Docket No. 65321(54558)

***Request for Interview***

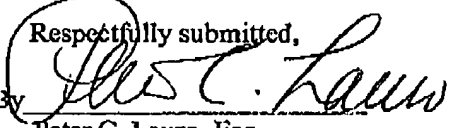
Applicant's representative requests a telephone interview with the Examiner once he has considered this response and prior issuance of a further official action on the merits. Applicant thanks the Examiner in advance for this courtesy.

**CONCLUSION**

In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of all rejections and allowance of the application with all pending claims. In the event the Office finds one or more of the present claims allowable, Applicant requests that the art of record be considered in view of full breadth of the claims; *i.e.*, not just the species elected by Applicant, for instance, testosterone-3-(O-carboxymethyl oxime)/HSA and taxol as the cytoskeletal acting drug (CAD).

The Director is hereby authorized to charge or credit any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105, under Order No. 65321(54558).

Dated: August 29, 2006

Respectfully submitted,  
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